

REMARKS

I. Scope of Claims.

The instant invention contains claims 1-6 and new claims 19-37 and are subjected to a restriction requirement by the Examiner. Applicants have amended claims 1, 3-4, 6 and 19-20 to place them in better form for examination. These amendments add no new matter and find support in the originally filed specification and claims.

II. Groups

In Paragraph 1 of the pending Office Action, the Examiner set forth a restriction requirement. The Office Action restricts pending claims as follows:

Group I: is drawn to a depot system containing one or more protein or peptide active substances, a drug comprising the same depot system and a method for administering the same depot system embodied in claims 1-6, 19-25, 35 and 37;

Group II: is drawn to a depot system containing oligonucleotide active substances embodied in claims 26-33;

Group III: is drawn to a depot system containing one or more water soluble active substances recited from a Markush group of claim 34, none of which are oligonucleotides nor protein or peptide active substances embodied in claim 34; and

Group IV: is drawn to a method of administering a depot system of the present invention comprising the step of one or both from the group consisting of topical and local application to support healing processes embodied in claim 36.

III. Restriction.

Applicants provisionally elect, with traverse, Group I, currently embodied in claims 1-6, 19-25, 35 and 37. According to Section 803 of the M.P.E.P., restriction may properly be required between patentably distinct inventions if (1) the inventions are independent or distinct as claimed; and (2) there is a serious burden on the Examiner if restriction is not required. In this case, the entire patent system would be unnecessarily burdened with the additional applications required and the duplicative work this restriction demand entails.

Specifically, Applicants respectfully submit that there will not be a serious burden on the Examiner if restriction between the claims is not required because regardless of the claims prosecuted, the field of search for each of the identified species are closely related if not identical and will substantially overlap as the overwhelming majority of the search will be conducted in the same class. A separate field of search is shown to exist only when one of the distinct subjects can be searched in places where no pertinent art to the other subject exists. In this case, however, there is no indication that a separate field of search is required for the disclosed inventions in groups I-IV. Thus, Applicants respectfully contend that there will not be a serious burden on the Examiner if restriction is not required as the classification are so closely related and the field of search is similar and therefore Applicants respectfully request that this restriction requirement be withdrawn.

IV. Election of Species.

The Examiner further stated that the application contains claims directed to patentably distinct species of the claimed invention. These species were deemed by the Examiner to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The Examiner stated that the species were as follows:

1. A single specifically named saturated synthetic phosphatidyl choline OR a single specific combination of saturated synthetic phosphatidyl cholines selected from the Markush group recited in claim 1.
2. A single specifically named cationic lipid selected from the Markush group recited in claims 1-2; and
3. A single specifically named protein or peptide active substance as recited in claims 21-25.

Therefore, the Examiner is requesting that the Applicants elect a single species under 35 USC 121.

Applicants respectfully traverse this election of species requirement, however, provisionally elects the species of DPPC as phosphatidylcholine; DC-Chol as cationic lipid; and LHRH agonists as protein/peptide active substance.

Claims 1-6, 19-23, 25, 35 and 37 are readable upon the elected species.

Applicants respectfully suggest that the instant election of species requirement is improper as the Examiner has failed to set forth reasons supporting such election. While the instant application has arguably multiple species of depot systems, the Examiner has not suggested or set forth that this number of species is unreasonable. Applicants respectfully submit that the instant case has a relatively small amount of species that do not require a burdensome classification, and/or bibliographic, manual and computer search by the Examiner.

Applicants further submit that there will not be a serious burden on the Examiner if election of species is not required because regardless of the claims prosecuted, the field of search for each of the identified species will substantially overlap, if not be identical to the other, as the species claimed all relate to a depot system for delayed release of active substances. A separate field of search is shown to exist only when one of the distinct subjects can be searched in places where no pertinent art to the other subject exists. In this case, however, there is no indication that a separate field of search is required for each of the disclosed species. Thus, Applicants respectfully contend that there will not be a serious burden on the Examiner if election of species is not required and would therefore respectfully request that this species election be withdrawn.

CONCLUSION

The claims remaining within the application are believed to patentably distinguish over the prior art and to be in condition for allowance. Early and favorable consideration of this application is respectfully requested.

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Respectfully submitted,

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